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Smith+Nephew RENASYS[®] EDGE Clinician User Manual

REF 66803126

Smith+Nephew RENASYS[®] EDGE

Negative Pressure Wound Therapy

Clinician User Manual

RENASYS EDGE Pump 66803126 only



Rx only

66803167
43229
11/2025



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Introduction

This user manual contains important information regarding the safe and effective operation of the RENASYS EDGE Negative Pressure Wound Therapy (NPWT) Pump. This pump is only to be prescribed by a clinician and is intended for use by, or on the direction of, a trained and licensed physician. This manual is intended to aid in the training of personnel and to provide a reference for experienced users. Also included are instructions for operating the pump, preventative maintenance, cleaning and return of the pump. This user manual is intended only as a guide. For medical questions, please consult a physician.

Intended Environmental Settings

The RENASYS EDGE Pump is intended for use in acute care settings and other professional healthcare environments where product use is conducted by or under the supervision of a qualified clinician. The pump is also intended for use in home healthcare settings where product use is conducted by or under the supervision of a qualified clinician. To ensure that the pump is safe for use in residential settings, this pump is compliant with the IEC medical equipment and medical electrical safety standard IEC 60601-1-11 for use of medical devices in the home healthcare environment. This standard includes the use of a double insulated Class II power supply.

Information For Your Patients

Prior to discharging your patient with the RENASYS EDGE Pump and User Manual, listed below are some topics they should know. These topics are covered in both the clinician and home healthcare user manuals.

- Introduction (Warnings + Precautions)
- Pump Description and Navigation
- Pump Setup
- Alarm, Alerts and Troubleshooting
- Accessories

Patient training on these topics will enable the patient to use the RENASYS EDGE Pump safely and effectively at home. Following training, patients should be able to successfully troubleshoot issues that arise, this will allow them to get the most benefit out of their treatment while at home.

Important Information Monitoring Negative Pressure Wound Therapy

- **Review Contraindications, Warnings & Precautions before use.**
- Carefully monitor the patient, pump, and dressing to determine if there are any signs of bleeding, exudate accumulation (pooling), infection, maceration, or loss of NPWT.
- The frequency should be determined by the clinician based on individual characteristics of the patient and wound. NPWT pumps are not designed to detect or issue an alarm condition based on the presence of bleeding or pooling. These conditions may only be detected by frequent monitoring.

Special attention to the risks of bleeding or loss of NPWT should be considered when prescribing for use in the Home Environment.

- NPWT may be impacted by various conditions related to pump, canister and tubing configuration, set-up and individual characteristics of the patient and wound (e.g. exudate characteristics, patient anatomy).
- Alignment of the port to the opening in the drape, use of a bridging technique and choice of dressing configuration based on wound characteristics may impact NPWT vacuum delivery over the course of therapy.
- Exudate volume, viscosity and consistency may influence the pump's ability to remove fluid or increase the chance of occlusion formation.
- A full canister and/or incorrect pump orientation can contribute to loss of NPWT and exudate accumulation within the wound, which could lead to maceration, infection, or bleeding.

Introduction (cont.)

- Monitor the wound for infection and ensure that all wound filler is removed at each dressing change to reduce the risk of infection. Skin grafts should be closely monitored to ensure Negative Pressure Wound Therapy (NPWT) is delivered.

Indications For Use

The RENASYS EDGE Pump is indicated for patients who would benefit from a suction pump (NPWT), as it may promote wound healing via removal of fluids, including irrigation fluids and body fluids, wound exudate and infectious materials.

Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Sub-acute and dehiscent wounds
- Ulcers (such as pressure or diabetic)
- Partial-thickness burns
- Flaps
- Grafts

Important information when using the RENASYS AB Abdominal Dressing Kit with Soft Port

When used with the RENASYS AB Abdominal Dressing Kit, the RENASYS EDGE Pump is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary. It is intended to be used in open abdominal wounds with exposed viscera, including but not limited to abdominal compartment syndrome. The use of RENASYS AB Abdominal Dressing Kit is intended for use in acute hospital care settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating theatre.

Contraindications

Use of the RENASYS EDGE Pump is contraindicated in the presence of:

- Untreated osteomyelitis
- Exposed arteries, veins, organs or nerves
- Necrotic tissue with eschar present
- Malignancy in wound (with exception of palliative care to enhance quality of life)
- Non-enteric and unexplored fistulas
- Exposed anastomotic sites

See Appropriate wound sites section on page 4.

Clinician Prescription

Prior to placement of the RENASYS EDGE Pump, the clinician treating the wound must assess how to best use the pump, canister and tubing for a wound. It is important to carefully assess the wound and patient to ensure clinical indications for NPWT are met.

All prescriptions should include:

- Wound location, size and type
- Smith+Nephew Wound Dressing Kit
- Pressure settings
- Frequency of dressing changes
- Adjunctive dressings



Warnings and Precautions

Before Use

General

- As a condition of use, the pump should only be used by qualified and authorised personnel. Users must have necessary knowledge of the specific medical application for which Negative Pressure Wound Therapy (NPWT) is being used.
- The product must be used in accordance with this user manual and all applicable labeling.
- Patient size and weight should be considered when prescribing therapy, particularly in **paediatric use**.
- Patients suffering from abnormal haemostasis or treated with anticoagulant therapy have an increased risk of bleeding. During therapy, avoid using haemostatic products that, if disrupted, may increase the risk of bleeding.
- Use RENASYS EDGE 300 ml Canisters with patients at high risk of bleeding.
- Due to its smaller diameter, the RENASYS-G 10Fr Round Drain Gauze Dressing Kit and Accessory Kit are not recommended for use with the RENASYS EDGE Pump, as reduced pressure in the wound bed may lead to pooling or maceration.
- Use of NPWT presents a risk of tissue ingrowth. Tissue in-growth may be reduced by:
 - reducing the level of pressure applied to the wound,
 - using a wound contact layer, or
 - increasing the frequency of dressing changes.

Appropriate wound sites

- The RENASYS EDGE System should only be used on wounds identified in the indications for use section. NPWT should not be applied to any wound types listed in the contraindications section.
- NPWT should not be placed directly over the patient's nerves, including the vagus nerve, as this could impact their functionality. To minimise risk of bradycardia, do not place NPWT in proximity to the vagus nerve.
 - Do not use directly on **exposed** blood vessels, organs or underlying structures.
 - Remove sharp edges** such as bone fragments or **cover** with non-adherent

gauze prior to initiating therapy, due to risk of puncturing organs or blood vessels drawn closer under the action of negative pressure.

- Cover** underlying structures, such as **bone, tendons, ligaments and nerves**, with natural tissue or a non-adherent dressing layer prior to applying the dressing to minimize the risk of damage from direct contact with the dressing.
- The RENASYS EDGE Pump should not be used for airway aspiration, or surgical suction or endoscopic closure of oesophageal anastomotic leak.
- The RENASYS EDGE Pump should not be used in the open abdomen, unless it is being used with the RENASYS AB Abdominal Dressing Kit and within a hospital setting.

Compatibility with antimicrobial dressings

- NPWT e.g. RENASYS EDGE, can be used in conjunction with ACTICOAT® FLEX Antimicrobial Barrier Dressings for a period of up to 3 days.

Two wound sites

- The RENASYS Y-Connector should not be used in the two wound configuration if one of the wounds is located in the open abdomen.
- When using a RENASYS Y-Connector, the patient should be monitored on a more frequent basis. The system will only detect a blockage if both connections are blocked. Regularly monitor the patient to ensure both dressings remain compressed.

During Use

Monitoring

- Monitor patients and canister contents for signs of bleeding. If active bleeding is observed, immediately **discontinue NPWT**, take appropriate measures to control bleeding and contact treating clinician.
- Monitor patient for any signs of local or systemic infection. As Negative Pressure Wound Therapy is not intended to directly treat infection, **contact treating clinician immediately** if there are any signs of systemic infection or advancing infection at wound area.

Warnings and Precautions (cont.)

- **More frequently monitor** the patient, pump and wound dressing, if patients are or may be:
 - Suffering from wounds in close proximity to blood vessels or delicate fascia,
 - Suffering from infected blood vessels,
 - Receiving anticoagulant therapy or platelet aggregation inhibitors, in addition to patients with intrinsic coagulation problems such as low platelet counts,
 - Actively bleeding, suffering from difficult wound haemostasis or have friable blood vessels or organs,
 - Suffering from untreated malnutrition, or
 - Non-compliant or combative.

Dressings

- Wound dressings should only be changed by clinicians and in accordance with the dressing change frequency stated in the dressing user manual. See dressing kit user manuals for instruction on dressing application and removal.
- The pump is only to be used with Smith+Nephew authorised components, dressing kits and accessories.

Accessories/AC power

- AC mains power can only be removed by disconnecting the AC power supply. Ensure pump can always safely be removed from mains power in an emergency situation.
- The electrical installation of the room must comply with the appropriate electrical wiring standards.
- Only use the power supply provided by Smith+Nephew to charge the pump. Use of any other products has not been proven safe and effective with the RENASYS EDGE Pump.

Hygiene and sterility

- Users should wash their hands before and after disconnecting the pump from the dressing to reduce the risk of cross contamination.
- RENASYS EDGE Pump, power supply and canisters are not provided sterile and should not be placed within a sterile field.

- Before disconnecting the pump from the dressing, to reduce the risk of cross contamination, ensure that the quick click connectors are held:
 - higher than the pump and wound, and
 - away from where wound fluid may contaminate the patient or other people.

Pump operation

- Do not use the pump or any accessories if they are damaged or do not function correctly. Contact your Smith+Nephew representative if the RENASYS EDGE Pump emits an unusual noise, the display does not function correctly, or if the power indicator does not illuminate when the pump is plugged into charge.
- Do not use the RENASYS EDGE Power Cord if any wires are frayed or exposed. Contact your Smith+Nephew representative for a replacement.
- Do not attempt to dismantle or modify the pump or any accessories. No maintenance can be performed by patients or caregivers.
- Do not operate the pump self-test feature in a dusty environment as it may damage the pump.
- Do not swallow any small parts removed from the pump.

Showering

- The pump and power supply contain electronic components and cannot be exposed to water. If water or other liquids get into the pump, turn it Off and consider changing the pump. If failure still occurs contact Smith & Nephew Medical, Ltd.
- When bathing or showering the patient, you must disconnect the pump and protect both ends of tubing using the tethered caps.

Pump placement

- Position pump, tubing and cables appropriately so that they do not wrap around the patient's neck or limb or cause a trip hazard. Be aware of tubing placement around children and animals.
- Ensure the patient cannot lie or sit on the pump and tubing as this may cause a pressure injury.

Warnings and Precautions (cont.)

- When pump is set at 25 mmHg consider placing pump and tubing at the same height as or below the wound. This will ensure the prescribed level of therapy is delivered.
- Keep out of reach of pets, pests and children.

Clinical decisions

- If the patient reports discomfort, consider reducing the level of pressure or use a wound contact layer. The pressure setting is a clinical decision based on individual characteristics of the patient and the wound. Factors to consider include:
 - location of the wound,
 - volume of the drainage,
 - integrity of the dressing seal.
- Negative Pressure Wound Therapy (NPWT) should remain on for the duration of the treatment. The length of time a patient may be disconnected from the pump is a clinical decision based on individual characteristics of the patient and wound. Factors to consider include:
 - location of the wound,
 - volume of the drainage,
 - integrity of the dressing seal,
 - assessment of the bacterial burden and patient's risk of infection.
- In the event a patient with spinal cord injury experiences autonomic dysreflexia, discontinue the use of NPWT and immediately seek medical assistance.

Other Equipment/Environments

- Due to danger of explosion, do not use the pump:
 - near an oxygen tank or oxygen generator,
 - within a Hyperbaric Oxygen (HBO) chamber,
 - near the source of any flammable gases, or
 - near any flammable disinfectants.

Canisters

- The RENASYS EDGE Canister should not be used for any other purposes than those described in this user manual.
- Canisters are for single patient use. Do not reuse.
- Canisters should be changed at least once a week, whenever there is a change in patient

or in the event that canister contents reach maximum volume indication (300 ml or 800 ml fill line). Do not wait for the Canister Full alarm to sound to change canister.

- Therapy should be paused when a canister is not fitted to the pump.

Ending Use

The pump has a self-test function which should be undertaken at least every six (6) months. After a period of 5 years, commencing on the date of delivery to the original buyer, if the pump does not pass the self-test, it has reached its end of life and it is no longer eligible for service or repair.

Disposal

- The pump should be returned to Smith+Nephew when no longer required by the facility. Smith+Nephew will dispose of the pump in accordance with the appropriate local regulations.
- The pump contains a lithium-ion battery that is not serviceable by the user. Improper disposal of the lithium battery may result in fire, explosion and burns.
- Do not puncture, crush, incinerate or expose the battery to temperatures exceeding 100 °C (212 °F).
- Handle damaged or leaking batteries with caution to avoid injury.
- Used canisters should be disposed of as clinical waste.

WEEE Directive [2002/96/EC] on Waste Electrical and Electronic Equipment. This statement only applies to European countries with regard to Waste Electrical and Electric Equipment (WEEE) European Directive.

The WEEE symbol on the product or its packaging indicates this product must not be disposed of with other waste. Instead, it is your responsibility to dispose of your waste equipment by sending it to a designated collection point for recycling of Waste Electrical and Electronic Equipment. The separate collection and recycling of your waste equipment at the time of WEEE will help conserve natural resources and ensure it is recycled in a manner that protects human health and the environment. For more information about where

Warnings and Precautions (cont.)

you can drop off your medical equipment at the end of its useful life for recycling, please contact your Smith+Nephew authorised representative.

MRI and Other Equipment Safety Information

- The pump is not diagnostic scanning compatible. Prior to entering the imaging suite, disconnect the pump from the RENASYS Dressing. The dressing can remain on the patient. The dressing is MR safe.
- The RENASYS EDGE Pump should be removed from the patient if it will interfere with the placement of monitoring equipment e.g. ECG probes.
- In the event defibrillation is required, disconnect the pump from the wound dressing. Remove the wound dressing only if its location will interfere with defibrillation.
- Remove the pump prior to diagnostic imaging e.g. X ray, CT and PET scanners. If the dressing may interfere with diagnostic imaging, it may also need to be removed prior to testing.

Pump Description and Navigation

The RENASYS EDGE Pump is a reusable, multi-patient-use Negative Pressure Wound Therapy (NPWT) pump. The pump connects to RENASYS Soft Port and RENASYS Dressing Kits manufactured by Smith+Nephew. The RENASYS Dressing Kits create a closed wound environment allowing for the delivery of NPWT. The pump has a Bluetooth® interface that allows connection to a smartphone or tablet device. The pump also contains a near-field communication (NFC) Tag interface allowing the S+N URL to be transferred to a Smartphone to gain access to further

pump information and help. The pump also detects canister presence and status through an internal near-field wireless connection.



The pump, the power supply, the canister and the canister tubing are not sterile.

The Pump, Canister and Tubing

The pump is designed to provide NPWT to a closed environment over a wound, in order to remove exudate from the wound site to a disposable canister, which may promote wound healing via removal of fluids, including irrigation and body fluids, wound exudate and infectious materials. The pump connects to a disposable canister which collects the exudate and keeps it away from the wound.

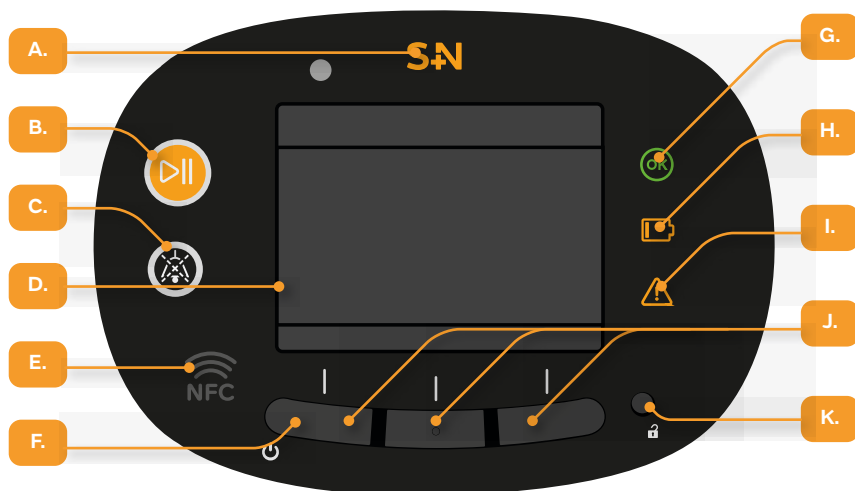
Dressings

The pump is only to be used with Smith+Nephew authorised components and dressing kits. Use of any other products has not been proven safe and effective with the RENASYS EDGE Pump. See dressing user manual and packaging for further information.

Wound dressings should only be changed by a clinician. Dressings should be changed in accordance with the dressing change frequency stated in the dressing's user manual and packaging.

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Pump Description and Navigation



A. The **Smith+Nephew logo** will illuminate when the pump is plugged in to a mains power supply.

B. The **Play/Pause button** is located to the left of the therapy screen, this is used to Start and Pause therapy when required. This button will illuminate when therapy is ready to be started.

C. When illuminated, the **Mute button** can be used to mute an alarm or alert.

D. The RENASYS EDGE Pump has a **fullcolour therapy screen**.

E. Place an NFC enabled phone over this area for a quick link to the manufacturer's website.

F. The **left multifunction button** is also the **power button** , the pump can be turned on and off by pressing and holding this multifunction button.

G. **System OK Light** indicates that therapy is On and everything is normal.

H. **Battery Warning Light** will indicate when the pump needs to be plugged in to a mains **power supply**.

I. **Alarm/Alert Light** will indicate when there is an alarm or alert state and attention is required.

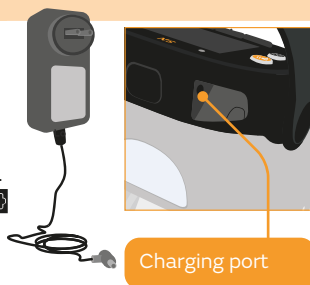
J. **Three multifunction buttons** are located underneath the screen. The functions of these buttons vary and are displayed at the bottom of the screen.

K. The **recessed Lock/Unlock button** is located to the right of the multifunction buttons. This is used by clinicians to lock the appropriate therapy settings for the patient.

Accessories

Power Supply

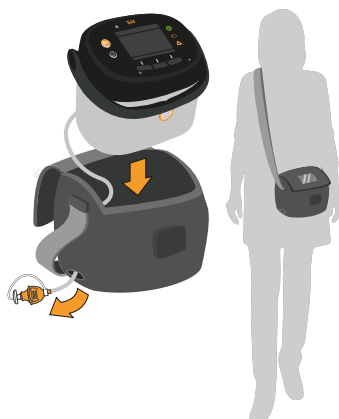
The RENASYS EDGE Pump operates on AC mains power and includes an internal battery allowing the patient to be mobile. Using the external AC power supply, the pump can be plugged into an electrical (AC) outlet to charge the battery. Charging will not interrupt active therapy. When the pump is connected to a power supply the **SN** logo on the face of the pump will illuminate. The battery indicator on the screen will display a lightning bolt  to indicate the battery is charging. The RENASYS EDGE Pump is designed to be used with RENASYS EDGE Power Supply only. The RENASYS EDGE Power Supply is not sterile.



Carry Bag

The carry bag is not sterile and for single patient use. Only use the Smith+Nephew carry bag with the pump. The bag will only accommodate a pump with the 300 ml canister fitted. To place the pump into bag:

1. Disconnect the canister tubing at the quick click connector and place tethered caps over the tubing ends.
2. Unclip the flap at the front of the carry bag.
3. Feed the canister tubing through one of the slots in the base of the bag.
4. Keeping the pump in the upright position place the pump into the carry bag, then put the carry handle in the forward position.
5. Reconnect the canister tubing to the dressing quick click connector.
6. Ensure the status lights on the face of the pump are visible through the clear window in the flap.



Caution: It is recommended not to charge the pump while it is in the carry bag as this may result in elevated operating temperature, which may cause the pump to suspend charging until it cools. The pump will still continue to operate. To reduce the operating temperature of the pump, remove it from the carry bag or move it into an environment with a lower ambient temperature. When the pump cools, charging will resume automatically.

Carry Straps/Adjustable Strap

The strap is not sterile and for single patient use.

To attach the strap to the pump:

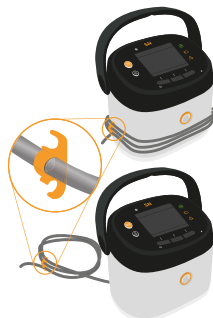
1. Slide the strap ends from below over the handle pivots at each side.
2. Pull up on the strap to secure in place.



Caution: Ensure the pump always remains in the upright position when using the straps.

Tubing Clip

The canister also comes with a tubing clip to assist with storage of excess tubing.



Pump Setup

Canister Selection

Only use Smith+Nephew RENASYS EDGE Canisters with the RENASYS EDGE Pump. RENASYS EDGE Canisters use an integral bacterial filter for protection of the pump against overflow and the spread of aspirated micro-organisms.

DO NOT REUSE CANISTERS. Canisters are designed for single patient use. Use of the canisters on more than one patient may result in cross contamination that could lead to infection.

Canisters should be changed at least once a week, whenever there is a change of patient, or when the contents reach the maximum volume indication (300 ml or 800 ml fluid

volume lines) in the viewing window. Check canisters regularly to monitor exudate levels, ensuring they are below the canister maximum volume indication. The canister should not be used independently of other means to monitor fluid.

Do not wait for the Canister Full alarm to sound to change canister.

Canisters are available in two sizes; 300 ml and 800 ml. For patients with high risk of bleeding, use the 300 ml canister. Canisters may have to be changed more regularly within single patient treatments if exudate levels are high.

Canisters are not sterile and should not be used in a sterile field.

Fluid volume lines



Caution: Position pump, tubing and cables appropriately so that they do not wrap around the patient's neck or limb or cause a trip hazard.

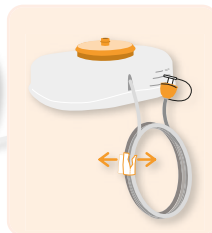
Caution: Do not use the pump without a canister fitted.

Caution: Monitor the canister and tubing for signs of bleeding or infection during use.

Installing a New Canister



1. Ensure therapy is paused or the pump is Off.



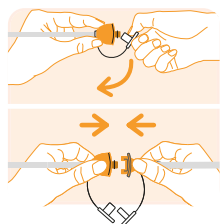
2. Remove the paper tape around the canister tubing and release tubing to full length.



3. Position the canister so that the tubing is facing to the rear of the pump then align the pump over the canister.



4. Push down on the pump until you hear a click from the release button.



5. Remove the caps from both quick click connectors and push them together until they click.

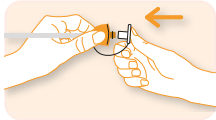
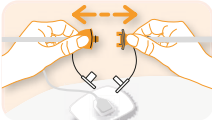
6. Start therapy by pressing .

Pump Setup

Removing/Changing a Canister



Caution: To avoid cross contamination, hold quick click connectors higher than the pump and wound, and away from other people when disconnecting.



1. If the pump is on and therapy is being delivered, pause it by pressing .
2. Holding the quick click connectors higher than the wound and pump, disconnect the canister tubing from the dressing tubing by squeezing the canister quick click connectors and gently pull the connectors apart.
3. Attach the tethered caps to both quick click connectors to protect the tubing and prevent leakage.
4. Press the release button, the button will click and the canister will come loose. Pull pump away from canister. To install a new canister see steps above. Once installed press  to restart therapy.

Check the new canister for any signs of cracks or damage. If noted, discard and replace the canister

Change or replace the canister if dropped or mishandled, even if no visible signs of damage are present, to ensure correct operation of software alarms for leak and blockage.

Canister Disposal

Ensure the quick click connector on the removed canister is capped before disposal. Disposal of used canisters should follow facility protocols or local regulations relating to handling of potentially infected or bio-hazardous materials.

Pump Orientation

The pump is designed to operate in the upright position. Operation in the upright position optimises canister volume and alarm functionality. The pump should be orientated to face the users when in stationary use.

Change or replace the canister if dropped or mishandled, even if no visible signs of damage are present, to ensure correct operation of software alarms for leak and blockage.



Correct orientation



Incorrect orientation

Pump Setup

Turning On/Off the Pump

- Ensure the battery is fully charged if battery operation is required for first use of the pump.
- **Press and hold** the left multifunction button  for 2 seconds to switch On the pump.
- To switch Off the pump press and hold the left multifunction button  until the screen asks 'Are you sure you want to power down the pump?'. Press the **Yes** button if you would like to turn Off the pump.
- On first time start up you will be prompted to set a language and the date. Please follow the on screen instructions and set the appropriate language and date. After this has been set, subsequent use of the pump will offer the user a brief RENASYS EDGE Pump tutorial screen.



To switch On or Off, press and hold the left multifunction button .

When the pump is due a self-test, a self-test notification will display when powering On the pump. To close this notification and continue to the therapy screen, press the **No** button.

Setting Therapy

The treating clinician will prescribe the therapy setting based on an assessment of the individual wound. These general guidelines should be adhered to:

- 40–125 mmHg is the recommended therapeutic pressure range.
- If the patient reports discomfort, consider reducing the pressure setting.
- Outside the recommended optimal

therapeutic pressure range of 40–125 mmHg, the broader operating range of 25–200 mmHg is provided to support clinical discretion on target pressure.

The pump will display the target pressure on the therapy screen.

Before starting therapy, check that the prescribed therapy settings have been properly set.

Caution: When pump is set at 25 mmHg consider placing pump and tubing level with or below the wound. This will ensure the prescribed level of therapy is delivered.

Lock/Unlock Feature

The lock/unlock feature is used by clinicians to lock the appropriate therapy settings to ensure patient safety.

- To Lock/Unlock therapy, press and hold the recessed Lock button  to the bottom right of the screen using a small blunt tool (e.g. pen) until the Locked/Unlocked screen is displayed. When locked, a  icon will show in the top right of the screen.



- Locking therapy will prevent the patient from changing the pump therapy settings.

When the pump is locked, the following settings cannot be used or changed: Intermittent/Continuous Mode, Y-Connector and Service Mode. All other functions are available.

The pump will lock after 2 minutes of therapy.

Pump Setup

Starting Therapy

Press the Play/Pause Therapy button  to start therapy. As the pump begins delivering therapy, it will display pump down progress and perform a leak check to determine if the dressing, canister and tubing is sealed. If a significant leak is detected in the dressing, canister or tubing, the pump will indicate a leak alarm. See **Alarms and Alerts** and **Troubleshooting** section for more details.

The compression rate is set at medium as a default but can be increased or decreased by pressing the **slower** or **faster** buttons. If the patient experiences pain, a slower pump down is advised.

When the pump is working correctly  will appear in the top left of the screen. When therapy is active and the pump is operating correctly a green swoosh will display below the target pressure setting. When the screen is in Power Saving Mode, System OK Light  will also appear on the face of the pump.

Pause Therapy

- Therapy can be paused by pressing the Play/Pause Therapy button .
- When paused  will show in the top left of the screen.
- If the pump is left paused for 30 minutes, it will produce a Therapy paused too long alert.
- If the pump is left paused for 60 minutes, it will automatically restart therapy.

During Use

When the pump is in use, always ensure it is positioned on a table or hung on an IV pole using the carry handle or strap of the RENASYS EDGE Pump.



Changing Basic Settings

To access the settings menu

- From the therapy screen, press the **Menu** button, scroll down using the  button to highlight **Settings**. Press the **Select** button to enter Settings.
- Scroll using the  and  buttons. Highlight the required settings then press the **Edit** or **Change** button.

To change the Date

- Use the  button to set the month. Use the  and  buttons to set the date and year. When the correct month date and year have been chosen press the **OK** button.

To change the Time

- Press the **Change** button to choose between **24hr** clock and **AM/PM** then press the **OK** button.
- Use the  and  buttons to set the hours and minutes.
- If using **AM/PM** use the  and  buttons to choose am or pm.
- When the correct time has been chosen press the **OK** button.

To change the Alarm Volume

- Press the **Change** button to choose between **Low**, **Med** (medium) and **High**. The pump will issue a sample tone as you make your selection.

To change the Brightness

- Press the **Change** button to choose between **Auto**, **Low**, **Med** (medium) and **High**.

To turn Bluetooth® On or Off

- Press the **Change** button to toggle Bluetooth® On or Off.
- When the Bluetooth® is turned On a Bluetooth® symbol  will display on the Status Indicator Bar.

To change the pump Language

- Scroll using the  button to highlight the appropriate language then press the **Select** button.

Pump Setup

Set Y-Connector

Toggling Y-Connector On or Off is unavailable when therapy is locked.

Ensure the Y-Connector Mode is On if:

- There are two dressings connected to the pump.

Setting Y-Connector On when only one dressing is connected to the pump may cause nuisance alarms.

Ensure the Y-Connector Mode is Off if:

- There is one dressing connected to the pump.

Setting Y-Connect Off when two dressings are connected to the pump may prevent the blockage alarm from sounding.

Caution: The pump will only detect a blockage if both connections are blocked and will not detect a blockage existing in only one of the Y-connected dressings. Therapy will not be delivered through the blocked dressing. Regularly monitor the patient during therapy to ensure both dressings are compressed.

To change Y-Connector settings

- If therapy is being delivered, pause therapy by pressing .
- Press the **Menu** button, scroll down using the  button to highlight **Y-Connector** then press the **Change** button to toggle the Y-Connector On or Off.
- The Y-Connector icon  will appear on the therapy screen if On has been selected.

Information on Continuous and Intermittent Modes

The pump features two therapy modes: Continuous and Intermittent.

Continuous Therapy Mode

In continuous mode, the pump will maintain the selected therapy level until therapy is stopped or changed. The target pressure is displayed in the center of the therapy screen. Therapy levels can be selected from a range of 25–200 mmHg by pressing the  or  buttons.

To turn Continuous Therapy Mode On

- If intermittent therapy is being delivered, pause therapy by pressing .
- Press the **Menu** button, highlight **Intermittent Mode** press **Change** to turn Intermittent Mode Off.
- A pop-up will show displaying 'The pump will apply continuous pressure', press **Continue**
- Press **Home**, then press  to start therapy.
- The continuous icon  will appear on the therapy screen.

Intermittent Therapy Mode

In intermittent therapy mode the pump will alternate between two target pressure levels at a set cycle time.

To turn Intermittent Therapy Mode On

- If continuous therapy is being delivered, pause therapy by pressing .
- Press the **Menu** button, highlight **Intermittent Mode** press **Change** to turn Intermittent Mode On.
- To change the intermittent mode settings press **Edit**.
- Use the ,  and **OK** buttons to set the desired intermittent mode settings.
- Review the settings on screen. Press **Continue** to begin therapy or **Edit** to change the settings.
- The intermittent icon  will appear on the therapy screen.

The compression rate cannot be altered in intermittent mode. Adjustments can not be made to intermittent mode when therapy is locked.

During Therapy

During treatment, you can access **Tutorials**, **Activity Logs**, **System Info** or **Settings** from the therapy screen by pressing the **Menu** button. Scroll down using the **✓** button to highlight your chosen item then press the **Select** button.

Tutorials

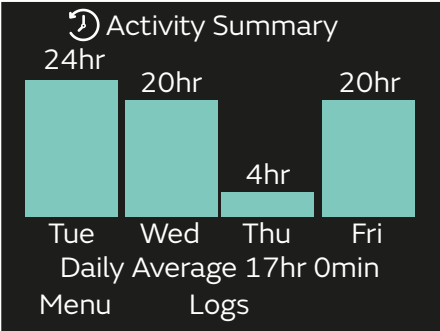
The RENASYS EDGE Pump contains tutorials that provide guidance on many of the pump features. A list of available tutorials will show when **Tutorials** is selected.

- Scroll through the list using the **✓** button, highlight the tutorial you would like to watch then press the **Select** button.

Activity Logs

Activity Logs display the pump activity since it was last reset. The pump is reset when the **Restore Defaults** option is selected, which can be found in **Service Mode**.

- Select **Activity Logs** to see the Activity Summary over the last four days.



- To scroll through the individual activity summaries of each day press the **Next** button.
- To view a more detailed list of the activity logs press the **Logs** button.

System Information

System Info displays a list of information, which includes: the date of the last self-test, the serial number, the software version, the operational time, the pump health, the battery health, regulatory information and patent information.

To scroll through this information, press the **Next** and **Back** buttons.

Power Saving Mode

The RENASYS EDGE Pump will enter power saving mode after 120 seconds of inactivity. The screen display will turn off to conserve battery life. Press any multifunction button to wake the display.

PICO® Single Use Negative Pressure Wound Therapy System Transition

When the RENASYS EDGE Pump detects that the canister was changed without filling up to its capacity, the pump may provide a recommendation for the clinician to either:

- Consider changing the canister less frequently, or
- Transfer the patient to PICO Single-Use Negative Pressure Wound Therapy (NPWT), if clinically appropriate

Preparing for a Shower

The pump and power supply operate electrically and must not come into contact with water. When showering ensure that the pump is paused and disconnected from the patient's dressing(s).

1. Pause therapy by pressing **⏸**.
2. Hold the tubing higher than the wound then disconnect the canister tubing from the dressing tubing by squeezing the canister quick click connectors and gently pull the connectors apart.
3. Close the tethered caps over both quick click connectors to protect both sides of tubing and prevent leakage.



Caution: When bathing or showering the patient, you must disconnect the pump and protect both ends of tubing using the tethered caps.

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Service and Maintenance

Service Mode

Service Mode has several options to aid the user when servicing or resetting the pump for use. These include:

- [View Service Guide](#)
- [Perform Self-Test](#)
- [Restore Defaults](#)
- [View Error Logs](#)

Scroll down using the **▼** button, highlight the option you want then press the **Select** button.

Service mode is unavailable when therapy is locked.

[Restore Defaults](#) should be selected whenever the pump is being prepared for use with a new patient.

- Scroll down using the **▼** button, highlight the [Restore Defaults](#) then press the **Select** button
- Press **Confirm** to restore the pump to the factory presets
- Press **Cancel** to maintain the current settings.

Caution: Never attempt to service the pump while connected to the patient.

Do not attempt to dismantle or modify the pump or any accessories. No maintenance can be performed by patients or caregivers.

Self-Test

The pump has a self-test function that provides information on the pump's health. The self-test function allows users to perform self-checks and will report a failure: if a technical fault is detected.

A self-test is due after two weeks without use, or every six months during use. If a self-test is due, a notification will display every time the pump is powered on.

- It is advised that clinicians carry out the self-test when prompted on start-up. Patients are advised to press **No** when prompted, skip the self-test and inform their clinician that a self-test is due.
- A self-test should also be carried out between patients.

Please follow the instructions on the screen to carry out the self-test. The button test has a 15 second time out, and if not pressed in that time, the self-test will report as a failure. If the self-test is carried out and completed with no errors, the user can continue to use the pump. If the self-test has failed, please contact a Smith+Nephew representative.

A self-test cannot be performed when therapy is active or the pump is locked.

To initiate a self-test without a prompt, pause therapy and ensure the pump is unlocked (Use a small blunt tool to press the recessed lock/unlock button to unlock the pump – see page 12). Use the on-screen menu to select service mode, then choose self-test.

Caution: Do not operate the pump self-test feature in a dusty environment as it may damage the pump

Returning the Pump

Prior to returning the pump and power supply to your Smith+Nephew authorised representative, the pump and power supply must be cleaned according to the steps outlined under the **Cleaning** section of this user manual.

The pump and power supply should be returned within the original shipping carton or transit case. If returning the pump and power supply in a transit case, place the pump into the molded insert and place the power supply in the compartment as shown on the inside label.

Service and Maintenance

Caution: There are no repairable parts inside the pump. Do not attempt to open the pump. Contact your Smith+Nephew representative, distributor or authorised provider if repair is required. No modification of this equipment is allowed.

Battery Operation and Charging

To allow the user greater mobility, the pump contains a lithium-ion rechargeable battery. A fully charged battery will last for up to 24 hours.

If battery operation is required for first use of the pump, the battery requires a full charge. The battery must be charged with the power supply until the battery indicator is full.

Caution: Keep device away from direct heat sources during charging.

To charge the battery

1. Connect the power supply into the charging outlet on the pump.
2. Plug the power supply into an electrical (AC) outlet.
3. Confirm that the **SN** logo on the face of the pump is illuminating.

When the pump is fully charged and powered On  will show in the top right of the screen. The pump will indicate when the battery is low. A low battery will first give an alert. A critically low battery will sound an alarm and the Battery Warning Light  will illuminate. Plug the pump into an electrical (AC) outlet as soon as possible when a battery alarm occurs.

The battery can be charged both during pump operation without interrupting therapy and when pump is turned Off and not in use. It is recommended to keep the pump plugged in during use when the patient is not mobile. If the pump is fully charged and is not going to be used further, disconnect the power supply from the pump and electrical outlet.

If the **SN** logo is not illuminated when the pump is connected to mains power, contact your Smith+Nephew representative to replace the pump.

Operation and Storage Conditions

The RENASYS EDGE System and components should be kept within the environmental limits listed below.

Operating and Long Term Storage Conditions

Temperature	41 °F to 104 °F / 5 °C to 40 °C
Relative Humidity	15% to 93% RH
Atmospheric Pressure	700 mbar to 1,060 mbar

Short Term Storage and Transport Conditions

Temperature	-13 °F to 158 °F / -25 °C to 70 °C
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Some battery discharge will occur in storage, especially at high temperatures. It is recommended that the unit is fully charged before storing, and every 6 months while in storage. If battery operation is required for first use of the pump, the battery requires a full charge. The battery must be charged with the power supply until the battery indicator is full.

If the pump indicates that the battery is not fully charged after more than 4 hours of continuous charge, contact your Smith+Nephew representative or authorised provider.

Caution: If the pump has been stored at temperatures below freezing, it must be brought to room temperature prior to use or the pump may be damaged.

Between Patients

When the RENASYS EDGE Pump is prepared for a new patient the following maintenance activities must be performed:

- Cleaning,
- Disinfecting,
- Perform a self-test,
- Restore defaults settings (See **Service Mode** Section).

Cleaning

Caution: Do not use solvents or abrasives that will degrade plastic housing and rubberised push buttons or the screen.

Caution: Do not immerse/submerge any part of the pump in fluid or use an excessively wet cloth. No fluids should be allowed to enter the pump. If any liquids penetrate the pump, contact your local distributor.

Caution: If the device is damaged in any way, it must be returned to Smith+Nephew.

Cleaning the RENASYS EDGE Pump

Cleaning of the power supply and outer casing should be performed to remove any soil or debris whenever there is a change in patient in the following steps:

1. Turn Off the pump and disconnect from the AC power before cleaning and disinfecting to prevent electrical shock.
2. Wipe down the surface with a dampened cloth or disposable wipe. Warm soapy water or a neutral pH7 based detergent/ disinfectant or antimicrobial agent that is safe for use with plastics may be used.
3. Visually inspect the surface for debris or soils that have not been removed and repeat cleaning steps if necessary.

During use it is recommended that the surface of the pump be cleaned as soon as it is soiled, using a damp cloth or disposable wipe and then wiped dry with another cloth or disposable wipe. Always follow facility protocols or local regulations for cleaning and handling of potentially infected or biohazardous materials.

Cleaning the Carry Bag

Carry bags are for single patient use and should be discarded when the patient ends the treatment with RENASYS EDGE System.

Carry bags may be cleaned during the patient's treatment as follows:

1. Wipe clean using a soft cloth dampened with a warm water and mild soap solution. A soft brush may be used if necessary.
2. Wait one minute before wiping clean with a soft cloth dampened with water only.

Disinfecting the Pump

1. After cleaning, the RENASYS EDGE Pump may be disinfected using these recommended pre-saturated wipes:

- Accelerated Hydrogen Peroxide,
- Potassium Hydroxide,
- Sodium Hypochlorite (bleach)
- Quaternary Ammonium Chlorides
- 70% Iso-Propyl Alcohol
- Phenols

Follow manufacturer's instructions carefully.

2. Following disinfection, wipe down the pump with a damp cloth to remove residual chemical residues.

Alarms and Alerts

The RENASYS EDGE Pump is equipped with alarms and alerts to indicate an error which requires user intervention. In the event of an alarm or an alert, an audible tone will sound, an alarm/alert screen will display and the Alarm/Alert light  will illuminate.

Information on Alerts

An alert warns the pump user that there is a potential problem about to occur. If an alert occurs the pump will sound every 15 minutes until the issue is resolved. Alerts can be dismissed, however this will remove the alert screen but will not resolve the issue.

Information on Alarms

If an alarm occurs a hazard exists that needs to be attended to immediately to prevent therapy becoming compromised. If an alarm occurs the pump will sound every 20 seconds until resolved. In some cases the pump may temporarily stop delivering therapy until the issue has been resolved.

The following alarms allow the audible alarm to be muted for 15 minutes by pressing the mute button .

- Blockage Alarm
- Critical Leak Alarm
- Canister Full Alarm
- Canister Missing Alarm

If the cause of the alarm is not resolved within this time the audible alarm will recommence.

If the audible alarm has been muted and a new alarm state occurs, the audible alarm sounds, and the screen will display the new alarm. When multiple alarm states are present, pressing **Next** will alternate between alarm screens.

Caution: Alarms are not intended to replace physical inspection and monitoring of the pump, canister and tubing by clinicians.

There are scenarios that may occur during therapy that can impact alarm functionality. Therefore, it is important that the patient, pump and wound dressing are monitored regularly to ensure therapy is being delivered.

- When the Y-Connector is connected to two dressings and the Y-Connector mode is on, the pump will only detect a blockage if both connections are blocked. The pump will not detect a blockage existing in only one of the Y-connected dressings; meaning that therapy will not be delivered through the blocked dressings. Regularly monitor the patient to ensure both dressings are compressed during therapy (See the **Set Y-Connector** section for more information).
- The blockage alarm will occur when the pump detects a blockage between the canister and where the dressing tubing interfaces with the transparent film. The blockage alarm will not assert if the RENASYS Soft Port opening is not aligned with the dressing opening, or a blockage occurs within the wound dressing. Regularly check the dressing and tubing to ensure exudate is being gathered into the canister.
- If a blockage is present in the system and an air leak occurs between the blockage and the pump the alarm may not assert. Ensure that all connections are secure and there are no air leaks present. Potential sources of air leaks include:
 - Cracked or damaged canister.
 - Misplaced o-ring within the quick click connector or canister outlet.
 - Damaged or tear in the dressing tubing or quick click connector.
 Regularly check that the dressing still has compression.

If the pump indicates a High Vacuum Alarm or a System Failure Alarm, then the pump has stopped delivering therapy.

Troubleshooting

When an alarm sounds, the RENASYS EDGE Pump screen will display information about the alarm. The pump includes **Help** on how

to resolve each alarm. If the alarm can not be resolved using the **Help** function, the table below provides further troubleshooting advice.

Do not switch the pump off and on during an alert or alarm this will reset the pump and the alarm/alert will continue once therapy is resumed.

Blockage Alarm

What has happened? What to do next



The pump has detected one or more of the following:

- A blockage within the canister
- A blockage within the tubing
- The internal canister filter is covered with exudate. This may occur even if canister does not appear visibly full.

1. Press the **Help** button and follow the on-screen instructions. If alarm persists continue with steps below.
2. If therapy is set to 25 mmHg consider reducing the height of the pump in relation to the wound.
3. Disconnect the canister tubing from the dressing tubing by applying pressure to the canister quick click connector and gently pulling the connectors apart. Leave open the tethered cap of the canister quick click connector and close the tethered cap of the dressing connector.
4. If the alarm continues, the blockage exists within the canister. Replace the canister. Refer to **Removing/changing canister** section of manual for more details.
5. If the alarm resolves and one dressing is connected to the pump, press the PLAY/PAUSE button followed by the **OK** button to navigate to the therapy screen and ensure that Y-CONNECT is not presented on the lower left of the therapy screen. If it is, press **Menu** and turn off the Y-Connector toggle. Reconnect the quick click connector and restart therapy. If the alarm continues there is a blockage in the dressing tubing. Reassess and replace as needed.
6. If the alarm resolves and two dressings are connected to the pump, then reconnect the quick click connector and restart therapy. If the alarm continues there is a blockage in the dressing tubing. Reassess and replace as needed, and ensure the Y-connector mode is reset to on if appropriate.
7. **If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith & Nephew Medical, Ltd.**

Canister Full Alarm

What has happened? What to do next



The pump has detected that the canister is full.

1. Press the **Help** button and follow on screen instructions. If alarm persists continue with steps below.
2. Ensure the pump is orientated correctly, in an upright position.
3. Pause therapy by pressing **>||**. See **Removing/changing canister** on page 11 for instructions.
4. **If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith & Nephew Medical, Ltd.**

Canister Missing Alarm

What has happened? What to do next



The pump cannot detect a correctly connected canister.

1. Press the **Help** button and follow on screen instructions. If alarm persists continue with steps below.
2. Pause therapy by pressing **>||** and reattach or replace canister. See **Removing/changing canister** section for instructions.
3. **If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith & Nephew Medical, Ltd.**

Troubleshooting

Moderate Air Leak Alert and Critical Air Leak Alarm

What has happened?	What to do next
 The pump has detected an air leak: • The pump will provide an alert when a moderate leak is detected • The pump will provide an alarm when a critical leak is detected. The pump will continue to operate but may not provide prescribed therapy. • See Alarms and Alerts section for more information.	 1. Press the Help button and follow on screen instructions. If alarm persists continue with steps below. 2. In the event of an air leak, the flow meter will display on the therapy screen to assist in locating leaks in the pump, canister and tubing. Follow the instructions on screen to resolve the issue. 3. Do not pause therapy or switch off the pump while resolving this alarm; the following steps will help identify the source of the leak. 4. Look for loose or decompressed dressing appearance, listen for air movement around the dressing and feel for areas less compressed. 5. Disconnect the canister tubing from the dressing tubing by holding the connectors above the level of the pump and patient's wound. Apply pressure to the canister tubing quick click connector and gently pull the connectors apart. Close the tethered caps of both connectors. 6. If the alarm continues, a leak exists within the canister or at the canister to pump connection. Replace the canister. Refer to Removing/ Changing Canister sections of the manual for more details. 7. If the alarm resolves, a leak exists within the wound dressing or tubing. Reassess and replace as needed. 8. If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith & Nephew Medical, Ltd.

Low Battery Alert and Critical Low Battery Alarm

What has happened?	What to do next
 The pump will provide an alert when there is less than 2½ hours remaining and an alarm when there is less than 20 minutes remaining.	1. Press the Help button and follow on screen instructions. If alarm persists continue with steps below. 2. Plug the pump into an electrical (AC) outlet as soon as possible. The pump can be plugged into an electrical (AC) outlet to charge the battery without causing interruption to active therapy. 3. If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith & Nephew Medical, Ltd.

Pump Too Hot Alert or Alarm

What has happened?	What to do next
 The pump will provide an alert if the battery temperature is too high for charging, and an alarm if the running temperature is too high.	Attempt to reduce the pump temperature. 1. Press the Help button and follow on screen instructions. If alarm persists continue with steps below. 2. Remove the pump from any covering or bag. 3. Move the pump out of direct sunlight. 4. Make sure there are no air leaks, see Moderate and Critical Air Leak for more information. 5. If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith & Nephew Medical, Ltd.

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Electromagnetic Compatibility RENASYS EDGE Pump

High Vacuum / System or Battery Failure Alarm

What has happened?



The pump has detected a pump, internal or battery failure.

What to do next

1. Press the **Help** button and follow on screen instructions. If alarm persists continue with steps below.
2. Switch off the pump and attempt a restart.
3. **If the alarm persists after troubleshooting, note the failure code and consider changing the pump. If failure still occurs contact Smith & Nephew Medical, Ltd.**

Therapy Paused Too Long Alert

What has happened?



The pump has been paused for more than 30 minutes.

What to do next

1. Restart therapy by pressing  as soon as possible.
2. **If the alarm persists after troubleshooting, consider changing the pump. If failure still occurs contact Smith & Nephew Medical, Ltd.**

Unusual Noise

What has happened?

If the RENASYS EDGE Pump emits an unusual noise.

What to do next

Stop using the pump and consider changing the pump. If failure still occurs contact Smith & Nephew Medical, Ltd.

Power Indicator Does Not Display

What has happened?

The power indicator does not light when the pump is plugged in to an external power source to charge.

What to do next

Stop using the pump and consider changing the pump. If failure still occurs contact Smith & Nephew Medical, Ltd.

Pump does not switch on

What has happened?

The pump does not switch on.

What to do next

1. Plug the pump into mains power to charge the battery
2. **If the pump does not respond after charging, contact Smith & Nephew Medical, Ltd.**

Pump Starts or Runs Improperly

What has happened?

The pump appears to start improperly such as no start up animation or no sound or if the pump does not look as normal during run time.

What to do next

Stop using the pump and consider changing the pump. If failure still occurs contact Smith & Nephew Medical, Ltd.

Pump Damaged

What has happened?

Any part of the pump is cracked or appears damaged.

What to do next

Stop using the pump and consider changing the pump. If failure still occurs contact Smith & Nephew Medical, Ltd.

Electromagnetic Compatibility RENASYS EDGE Pump

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2 and tested according to the recommendations of IEC TS 60601-4-2. These limits and test levels are intended to provide reasonable safety with regard to electromagnetic disturbances when the pump is used in a typical medical installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.

Guidance and manufacturer's declaration – electromagnetic immunity

The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±6 kV, ±8 kV air ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV For power supply lines 100 kHz repetition frequency	±0.5 kV, ±1 kV, ±2 kV, ±4 kV For power supply lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial, home healthcare or hospital environment
Surge IEC 61000-4-5	±0.5 kV, ±1 kV Line-to-line ±0.5 kV, ±1 kV, ±2 kV Line-to-ground	±0.5 kV, ±1 kV, ±2 kV, ±4 kV Line-to-line ±0.5 kV, ±1 kV, ±2 kV Line-to-ground	Mains power quality should be that of a typical commercial, home healthcare or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 (NOTE UT is the a.c. mains voltage prior to application of the test level)	At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phases 0% UT (100% dip in UT) for 0.5 cycle At 0° single phase 0% UT (100% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles 5% UT (100% dip in UT) for 5 seconds 0% UT (100% dip in UT) for 250 cycles 0% UT (100% dip in UT) for 300 cycles	At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phases 0% UT (100% dip in UT) for 0.5 cycle At 0°, 180° phase 5% UT (100% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles At 0° single phase 70% UT (30% dip in UT) for 25/30 cycles 0% UT (100% dip in UT) for 5 seconds	Mains power quality should be that of a typical commercial, home healthcare or hospital environment. If the user of the pump requires continued operation during power mains interruptions, it is recommended that the pump be powered from an uninterruptible power supply or battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 or 60 Hz	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz In ISM and amateur radio bands	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz In ISM and amateur radio bands	Portable and mobile communications equipment should be separated from the pump by no less than distances calculated/listed below: Recommended separation distance: $d = 0.58\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	$d = 0.35\sqrt{P}$ (80 MHz to 800 MHz) $d = 0.7\sqrt{P}$ (800 MHz to 2.5 GHz)) where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol:
Proximity Mag. Fields IEC 61000-4-39	Spot test: 385 MHz. at 27 V/m; (710, 745, 780, 5240, 5500, 5785) MHz. at 9V/m; (450, 810, 870, 930, 1720, 1845, 1970, 2450) MHz. at 28V/m Spot test: 30kHz at 8A/m; 134,2kHz at 65A/m; 13,56MHz at 7.5A/m	Spot test: 385 MHz. at 27 V/m; (710, 745, 780, 5240, 5500, 5785) MHz. at 9V/m; (450, 810, 870, 930, 1720, 1845, 1970, 2450) MHz. at 28V/m Spot test: 30kHz at 8A/m; 134,2kHz at 65A/m; 13,56MHz at 7.5A/m	

NOTE 1: At 80 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.

To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the pump is used exceeds 3V/m, the pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the pump.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.



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Guidance and Manufacturer's Declaration

Electromagnetic Emissions RENASYS EDGE Pump (REF 66803126)

Guidance and manufacturer's declaration – electromagnetic emissions for the RENASYS EDGE pump (REF 66803126)

The pump is intended for use in an electromagnetic environment in which radiated RF disturbances are uncontrolled and the Class II power supply is used.

Emissions test	Compliance	Electromagnetic environment - guidelines
RF emissions CISPR 11	Group 1	The pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The pump is suitable for use in all establishments including domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Comply	

WARNING: The pump should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the pump should be observed to verify normal operation in the configuration in which it will be used.

Do not use cables and accessories other than those specified or sold by Smith+Nephew as it may result in increased electromagnetic emissions or decreased electromagnetic immunity of the RENASYS EDGE pump. Portable and mobile RF communication devices (mobile telephones) can affect the RENASYS EDGE pump. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the RENASYS EDGE pump (REF 66803126), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The pump is intended for use in an electromagnetic environment in which radiated RF disturbances are uncontrolled and the Class II power supply is used. The customer or the user of the pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the pump as recommended below, according to the maximum output power of the communications equipment.

Recommended separation distances between portable and mobile RF communications equipment and the pump.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m):		
	800 MHz to 2.7 GHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
	d = 0.58√P	d = 0.35√P	d = 0.7√P
0.01	0.06	0.04	0.07
0.1	0.02	0.11	0.22
1.0	0.6	0.35	0.7
10	1.8	1.11	2.21
100	5.8	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Specification

Essential Performance			
Essential performance of the RENASYS EDGE Pump, for safe operation, is to maintain the vacuum delivered by the pump within its specification for pressure selected, to provide Negative Pressure Wound Therapy (NPWT). Contact your Smith+Nephew representative, distributor or authorised provider if service or additional guidance is required.			
Vacuum			
Continuous Therapy Levels	25, 40, 60, 80, 100, 125, 150, 175, 200 mmHg		
Intermittent Therapy Levels	High: 40, 60, 80, 100, 125, 150, 175, 200 mmHg Low: 25, 40, 50 mmHg		
Intermittent Therapy Cycles Times	High 5, 8, 10 mins Low: 2,3,5 mins		
Alarms			
Frequency	20 seconds		
Priority	Low		
Auditory Sound Level	Low: 58 dB Medium: 68 dB High: 75 dB		
Indicator Colour	Yellow		
Overall Alarm Delays			
Over Temperature	60 seconds	Canister Full	120 seconds
High Vacuum	360 seconds	Critical battery	60 seconds
Leak/Low vacuum	45 seconds	Battery failed	300 seconds
Blockage	300 seconds	Pump failed	2 seconds
Canister Missing	45 seconds		

All of RENASYS EDGE System components and dressings are considered applied parts. All of the applied parts are type BF (body floating) defibrillation proof parts.

Power Requirements	
Power input voltage	+12 V
Pump input power	25 W
Mains Adapter	Input: 100-240 V~, 50-60Hz, 1.2 A(1.2 A-0.5 A) Output: +12V
Physical	
Dimensions	150W x 135H x 110D with 300 ml canister
Weight	1.13kg with empty 300ml canister fitted
Battery	
Operating time	>24 hours (therapy) when operating at 125mmHg
Type	Lithium-ion
Compliance	UL 2054/IEC62133
Safety Protection	
Protection against electric shock	Pump internally powered; external power supply, Class II.
Patient protection	Defibrillation proof type BF
Ingress protection	IP34 Enclosure protected ingress of small objects (>2.5 mm in width) and light water spray.
Compliance	
Certified to: CSA STD C22.2 No 60601-1	
Conforms to: ANSI/AAMI STD ES60601-1 IEC STD 60601-1-6,	
IEC STD 60601-1-8, IEC STD 60601-1-11	
Evaluated to: IEC STD 60601-1, IEC STD 60601-1-2, IEC TS 60601-4-2	
Maximum Pump Temperature (°C)	
LCD screen	52.1 °C
USB compartment	52.2 °C
Rear lower housing	43.7 °C
Warming and Cooling time	
The pump will require 45 minutes to warm from -25 °C at 20 °C	
The pump will require 29 minutes to cool from 70 °C at 20 °C	
Wireless interfaces	
Bluetooth® 5 Class 2 interface	
Type 2 NFC-A tag interface	

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Replacement Parts and Accessories

The following products are available from Smith+Nephew. Contact Smith+Nephew customer assistance for availability and ordering information.

New Item Description	SKU number
RENASYS EDGE Pump	66803126
RENASYS EDGE 300 ml Canister with Solidifier	66803139
RENASYS EDGE 800 ml Canister with Solidifier	66803140
RENASYS EDGE 300 ml Canister without Solidifier	66803141
RENASYS EDGE 800 ml Canister without Solidifier	66803142
RENASYS EDGE Carry Straps	66803137
RENASYS EDGE Adjustable Strap	66807720
RENASYS EDGE Carry Bag	66803136
RENASYS EDGE Transit Case	66803138
RENASYS EDGE Plug-in Main Adapter Type A (North America, Japan)	66803146
RENASYS EDGE Plug-in Main Adapter Type G (UK)	66803147
RENASYS EDGE Plug-in Main Adapter Type I (Australia, New Zealand, China)	66803149
RENASYS EDGE Plug-in Main Adapter Type C (Europe, South America, Asia)	66803150
RENASYS EDGE Plug-in Main Adapter Type A-CN (China)	66807689
RENASYS EDGE Plug-in Main Adapter Type M (South Africa)	66807690
RENASYS EDGE Plug-in Main Adapter Type F (South Korea)	66807706
RENASYS EDGE Clinician Manual	66803167
RENASYS EDGE Home Healthcare Manual	66803168
RENASYS Y-Connector	66800971

Wireless Quality of Services

The RENASYS EDGE Pump overall wireless Quality of Services is implemented accordingly with three wireless communication functions. The RENASYS EDGE Pump has two types of wireless communications interfaces: One Bluetooth® Low Energy (BLE) and two NFC. The Bluetooth® interface uses the legal manufacturer UUID and follows the Bluetooth® 5 specification utilizing frequency hopping, latency and error correction. It also employs encryption to keep the data secure. The maximum communication range is around 20m. If BLE errors are detected, the RENASYS EDGE Pump may respond in one or two ways:

- The pump could regard the error as fatal and abandon the communication, or
- Request or hint that the transmitter should send the data again in the hope that a subsequent attempt is successful.

The two NFC communication interfaces are ensured by using close range communications less than 50mm, reducing the likelihood of interference. The NFC in the top of the RENASYS EDGE Pump communicates in close proximity to the external smart device and to transfer URL. The internal NFC located in the bottom communicates with the Canister to transfer canister configuration and status information.

- Bluetooth® 5 Class 2 interface – UHF radio waves in the ISM bands, from 2.402 GHz to 2.48 GHz ERP (Effective Radiated Power) 1mW
- Type 2 NFC-A tag interface – 13.56 MHz, up to 4cm range

Wireless Coexistence

RENASYS EDGE Pump was tested for wireless coexistence for Tier 3 indicating a high likelihood of coexistence following the guidelines and test results from ANSI C63.27:2021.

RED (Radio Equipment Directive) Statement

Declaration of Conformity Hereby, Smith & Nephew Medical, Ltd., declares that the RENASYS EDGE Pump is in conformity with the essential requirements and other relevant requirements of the Directive (2014/53/EU) and the DoC in the language of the manufacturer. The RENASYS EDGE Pump is marked with the CE marking as required by the Council Directive 2014/53/EU with the involvement of CETECOM GmbH Notified body: **CE**

- Bluetooth® / Bluetooth® LE – Modulation GFSK, from 2400 – 2483.5 MHz, EIRP ≤ 20 dBm.
- Type 2 NFC-A tag interface – Modulation ASK, 13.56 MHz, up to 4cm range, ≤ 9 dBμA/m @ 10m

Intended location of wireless operation

This equipment may be operated in:

BE	BG	CZ	DK	DE	EE	IE	EL	ES	FR	HR	IT	CY
LV	LT	LU	HU	MT	NL	AT	PL	PT	RO	SI	SK	FI
SE	NO	IS	LI	CH	TR	UK(NI)						

IC (Industry Canada) Statement (IC 26135-EDGE)

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1. L'appareil ne doit pas produire de brouillage;
2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Canadian Department of Communications Compliance Statement CAN ICES-3(B)/NMB-3(B)

FCC Compliance (FCC ID 2AWH9-EDGE)

Modifications not expressly approved by Smith+Nephew could void the user's authority to operate the equipment. Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Radio frequency radiation exposure information
For body worn operation, this device has been tested and meets the FCC RF exposure guidelines when used with the Smith+Nephew accessories supplied or designated for this product. Use of other accessories may not ensure compliance with FCC RF exposure guidelines. This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Cyber Security Labelling

There are no specific user accounts or passwords required for standard operation of the device. The device is designed to be a standalone non-networked device. It is not intended to connect to any wired or non-wired networks.

The Bluetooth function is disabled by default, but this can be enabled. However, there is no option to connect or pair another device. The Bluetooth design function is to facilitate future sharing of device system information for inventory purposes. We recommend the Bluetooth function should remain disabled.

The USB port is disabled for use by the end user. It has a screwed-on cover and can only be used in conjunction with an encrypted maintenance and diagnostic tool used by an authorized service center.

If this cover is damaged or is not in place, then please contact your S+N representative.

The software and firmware can only be updated by an authorized service center. Do not attempt to dismantle or modify pump or any accessories. No maintenance, updates or upgrades can be performed by patients or caregivers.

To determine which version of software or firmware is installed, please refer to the System Information section of the manual. To establish if the pump is running correctly, please refer to the “What the Pump Looks Like When Running Correctly” section.

In the event of a software or hardware failure please refer to the Troubleshooting section in the manual. If the failure remains unresolved contact your S+N representative.



The RENASYS EDGE Pump has the following interfaces and ports:

Interface/Port	Protocol	Function/data type	Intend use
NFC Tag Interface for Canister	N/A	Non-sensitive equipment operational, telemetry information is shared bidirectionally. However, all Data exchange only happens internally, there is no external data exchange with other devices during normal use. – Non real time remote control	To detect the presence of a canister and the fill level of the attached canister. This is only for internal use by the device itself. This NFC TAG is not pairable and is disabled for any other interaction.
Type 2 Tag Interface	N/A	Non-sensitive equipment operational, telemetry information is shared unidirectionally outbound from the device. There is no real time remote control possible.	To allow a smartphone to transfer to the S+N corporate URL to gain access to further pump information and help pages for the device. This interface is intended for users.
Bluetooth® Interface	Bluetooth® 5.1 specification	Non-sensitive equipment operational, telemetry information is shared unidirectionally outbound from the device. There is no real time remote control possible.	It is used only to provide device operational data, or to read the device settings. Bluetooth® is disabled by default “out of the box”. There is no ability to pair with another device using Bluetooth®.
USB Interface	AES-128 encryption and session key	Non-sensitive equipment operational, telemetry information is shared bidirectionally. In standard operation mode Non real time remote control. In diagnostics / upgrade mode, updates and diagnostic data gathering is completed via a wired connection.	The USB interface is available in CDC mode for diagnostics and service purposes and is disabled for use by the end user. It has a screwed-on cover and can only be used in conjunction with an encrypted maintenance and diagnostic tool used by an S+N engineer.

Warranties

LIMITED WARRANTY

For Warranty Terms and conditions, please refer to your country specific element at the following link:

<https://www.smith-nephew.com/en/product-terms-conditions-and-warranties>

Icon and Symbol Glossary

Pump buttons

	Play/Pause button
	Mute Button
	Canister Release Button
	Recessed Lock/Unlock Button
	Three Multifunction Buttons

Pump lights

	System OK Light
	Battery Warning Light
	Alarm/Alert Light
	External Power Indicator

Battery icons

	Full Charge Battery
	Low Battery
	Critical Low Battery
	Charging
	Fully Charged
	Battery Failure

Therapy screen icons

	Y-Connector Mode
	Intermittent Mode
	Continuous Mode

Status bar icons

	Paused
	System OK
	Alarm/Alert
	Critical Air Leak
	Moderate Air Leak
	Blockage
	Canister Missing
	System Failure/High Vacuum
	Pump Too Hot Alert
	Pump Too Hot Alarm
	Paused Too Long
	Canister Full
	Locked
	Bluetooth On
	Muted

- EN
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Icon and Symbol Glossary

Additional symbols

For additional wireless symbols visit <https://ifu.smith-nephew.com/> and enter the RENASYS EDGE Pump SKU 66803126 when prompted.

	Direct current		Medical Device
	Alternating current		Unique Device Identifier
	International classification		Humidity limitation
	Manufacturer		Keep away from sunlight
	Follow instructions for use		Atmospheric pressure limitation
	Consult instructions for use. Electronic instructions for use available at: ifu.smith-nephew.com		Serial number
	Caution		Do not re-use
	Do not use if package is damaged		Batch code
IP34	Enclosure protected against ingress of small objects (>2.5 mm in width) and light water spray		MR Unsafe - Keep away from magnetic resonance imaging (MRI) equipment
	Keep dry		Catalogue number
	Temperature limit		Federal Communications Commission Identifier
	Date of manufacture		Near-field communication (NFC)
Rx only	Caution: U.S Federal law restricts this pump to sale by or on order of a physician		Biological waste symbol
	Defibrillation-proof type BF applied part		CE mark for radio equipment directive (RED) 2014/53/EU
	Intentional Radiator		EU: WEEE 2012/19/EU symbol not for general waste
	CE Mark		UK Conformity Assessed (wireless) RER SI 2017/1206
	Authorized representative in the European Community/European Union		

Smith+Nephew Customer Care contact details

Ireland	24 hours Language: English	Tel: 1800 30 36 22
United Kingdom	24 hours Language: English	Tel: 0800 9155 394
Canada	24/7 Clinical Hotline and Customer Care Center	Tel: 1-800-463-439